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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/078,949	02/20/2002	Stanley T. Crooke	ISIS-5027	8454

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EXAMINER

MCGARRY, SEAN

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 08/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/078,949

Applicant(s)

CROOKE, STANLEY T.

Examiner

Sean R. McGarry

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 May 2005.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 94,97-103,105,108-111,122,123,125,126 and 158 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 94, 97-103, 108-111, 122, 123, 125, 126, 158 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 94-98, 100-102, 104-111, 113, 121, and 123-125 **were** rejected under 35 U.S.C. 102(b) as being anticipated by Agrawal [WO 94/01550].

This rejection has been withdrawn in view of applicants amendments to the claims.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 157 and 158 **were** rejected under 35 U.S.C. 103(a) as being unpatentable over Agrawal as applied to claims 94-98, 100-102, 104-111, 113, 121, and 123-125 above, and further in view of Hunziker and Leumann, Nucleic Acid Analogues: Synthesis and Properties in Modern Synthetic Methods 1995, ed. Ernst and Leumann, pages 331-417, 1995.

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This rejection has been withdrawn in view of applicants amendments to the claims.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 122 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 122 depends from canceled claim 121 rendering the claim vague and indefinite.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 94, 97-103, 105, 108-111, 123, 125, 126, and 158 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant points to pages 6-8, 9-14, 17, 18, 20, 21, 24, 27, 30, 91, 92, and

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94-96, Figure 4 and Claim 1 as originally filed for support for new claims 94-154, filed as a preliminary amendment with the application. Applicant points to pages 4, 6-14, 17, 18, 20-27, 30, 32, 91, 92, and 94-96, Figure 4, and claim 1 as originally filed for support for new claims 155-164 filed 4/11/02. Applicant provides no specific direction where support can be found for any particular claim or limitations introduced in the preliminary amendments.

The above claims all contain new matter. Claims 94, 97-103, 105, 108-111, 123, 125, 126, and 158 are all drawn to methods of modifying a target RNA, activating a nuclease within a cell, or modulating the levels of a target RNA via the contacting of a cell with a **double stranded RNA** that contains a modification. The specification is drawn to "**oligomeric compounds formed from a linear sequence of linked ribonucleoside units that are specifically hybridizable to a preselected RNA target.**" (See page 6 of the instant specification). Furthermore, the specification discusses the properties of single stranded RNA or RNA-like oligomeric compounds that **form double strands with a target RNA** and are cleaved by a specific dsRNase (see page 16, lines 22-29, for example). The examiner was at a loss to find any support for a double stranded compound was contacted with a target RNA for modification or modulation.

It is noted that pages 90-94 describe the use of specific double stranded chemically modified sense and antisense oligonucleotides in an assay to detect dsRNase activity in cellular extracts. However there was no support found in the specification or claims as originally filed for any methods of activating a nuclease activity

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within a cell with double stranded RNA. The purpose of the examples was to isolate RNase activity from cellular extracts and it is unclear how this might be extrapolated to provide support for activating dsRNase in a cell.

It is clear that the specification does not describe what is claimed.

Applicant's arguments filed 6/05/05 have been fully considered but they are not persuasive.

Applicant argues that the specification provides adequate written description for that which is claimed. Applicant asserts that there is support for contacting a cell with double stranded RNA, activating a nuclease within a cell, or modulating the levels of a target RNA via the double stranded RNA. Applicant points to page 30 and assert that "target RNA" shall mean any RNA that can hybridize with a complementary nucleic acid compound and further assert that this complementary nucleic acid compound could be a first RNA [presumably from the double stranded RNA of the method claims]. Applicant then shows that the specification provides a definition for "complementary". Is applicant relying on a general definition of a biological term as support for their invention? Page 30 appears to provide a description/definition of a target RNA but it is unclear how it makes any description of a double stranded RNA that is used to modify that target RNA. Applicant asserts that the specification does not limit the formation of duplexes with mRNAs. The argument that the specification doesn't limit the genus is not a showing of or description of a particular species that may not be excluded from that genus.

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Nowhere has applicant actually pointed to any specific support or description for inhibiting a target RNA via a double stranded RNA.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

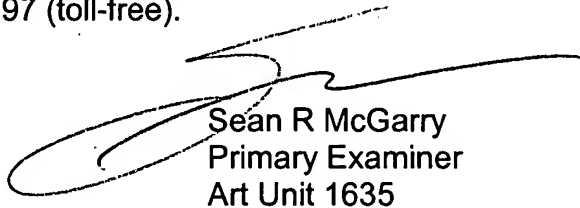
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean R. McGarry whose telephone number is (571) 272-0761. The examiner can normally be reached on M-Th (6:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Sean R McGarry
Primary Examiner
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